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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,834	04/04/2002	Jeremy Marshall	3003-1010	5293

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EXAMINER

WEBB, SARAH K

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,834

Applicant(s)

MARSHALL ET AL.

Examiner

Sarah K Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/4/02</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 2-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the cap having projections that fit with abutments on the lancet, does not reasonably provide enablement for a connection formed as a screw thread, bayonet, or snap fit. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The figures only support an embodiment that forms the connection between the lancet and cap as projections on the cap that interlock with abutments on the lancet body. The figures do not provide support for connection means formed by screw threads, bayonet, or snap fit.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 5,324,303 (Strong et al.) in view of US Patent No. 3,651,972 (Itoh).

Strong discloses a combined lancet and cap device. As best shown in Figure 3, the cap (5) is integrally formed with the lancet body (3) at connection piece (11). Strong explains that the cap and lancet are integrally moulded of plastic material (column 6, lines 44-46). The cap is designed to be detachable from the lancet body by twisting and pulling, so that the piece (11) will break at section (23) (column 6, lines 44-54). The cap conceals the needle tip (7) before removal, as in Figures 3 and 4, and then is connected to the lancet so that the needle (7) can pass through aperture (17), as in Figure 9C. The lancet body includes projections (13) that prevent it from rotating relative to the firing device (column 6, lines 1-5).

The cap includes two sets of projections (21 and 29) that are adapted to engage "abutments" defined on either side of grooves (25,27) on the lancet body (3) (column 6, lines 60-65 and column 7, lines 5-15) when both are removed from the firing device, as illustrated in Figure 9e. This is considered to meet the limitation "snap fit." As shown in Figure 3, the legs are bent inwardly to have a reduced diameter at the site of the projections, so that the projections will engage the abutments in the lancet when the cap is removed from the firing device. The legs are move outwardly to a larger diameter to fit over the circular end of the firing device.

Strong fails to form the cap to have an elliptical cross section at the site of the connection means. Itoh discloses a resilient cap (104) in Figure 6 that includes a connection means (111) on the inside surface that interlocks with another device (101). The opening of the cap has an elliptical cross section, as shown in Figure 7, and the connection means are located on minor axis. Itoh explains that the cap is squeezed

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along the major axis (P in Figure 10) to deform the cap to a more circular shape and disengage the connection means from the device (101). It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the cap of Strong to have an elliptical cross section, as taught by Itoh, as this structure allows the user to easily engage/disengage the connection means of a resilient cap with a device.

3. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strong in view of Itoh, as applied to claim 1 above, and further in view of US Patent No. 6,210,420 (Mauze et al).

The modified Strong device fails to form the connection between the cap and lancet by screw threads. Mauze discloses a lancet firing device with a cap (106) and teaches that the cap can be connected to the device (104) by screw threads (108). It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute screw threads for the projections of the modified Strong cap, as Mauze teaches that this is another way to form a connection means between a cap and a lancet firing device.

4. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strong in view of Itoh, as applied to claim 1 above, and further in view of US Patent No. 5,984,940 to Davis et al.

The modified Strong device fails to form the connection between the cap and lancet Z a bayonet fitting. Davis discloses a lancet firing device with a cap (48) and teaches that the cap can be connected to the device (30) by a bayonet fitting (column 9, lines 1-9). It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to substitute a bayonet fitting for the projections of the modified Strong cap, as Davis teaches that this is another way to form a connection means between a cap and a lancet firing device.

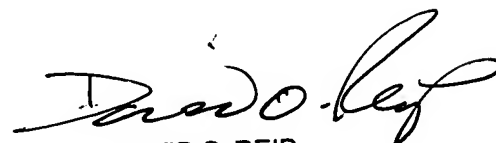
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah K Webb whose telephone number is (703) 605-1176. The examiner can normally be reached on Mon-Fri 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (703) 308-2154. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SKW
09/23/04



DAVID O. REIP
PRIMARY EXAMINER